

Application No.: 10/646,852
Filing Date: August 22, 2003

REMARKS

After entry of the present amendments Claims 2-8, 10-13, 16-22, 27, and 33-45 will be pending. New Claims 39-45 are added herein. Support for the new claims can be found in the specification and claims as originally filed, in particular paragraph [0059] of the specification as filed. No new matter is added.

Priority

In the Office Action the Examiner conclusively stated that "It is noted that provisional application 60/405791 does not correspond to the current application. Specifically, 60/405791 is not directed to the addition of a monovalent salt. Applicant is not entitled to the priority date of the provisional application." Office Action, page 2. Applicant respectfully disagrees with this conclusory statement and notes that the Examiner did not provide a claim by claim analysis of the priority. Even assuming *arguendo* that the provisional application does not disclose addition of a monovalent salt, at least Claims 38, 2-8, 10-13, 16, and 27 are entitled to priority because they do not recite a monovalent salt.

Carr Does Not Anticipate or Make Obvious Claims 2-8, 10-13, 16-22, and 38

The Examiner rejected Claims 2-8, 10-13, 16-22, and 38 under 35 U.S.C. § 102(e) as anticipated by WO 02/096208 to Carr or in the alternative under 35 U.S.C. § 103 as obvious over Carr.

Anticipation

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

Applicant also notes that "[i]nherency, however, may not be established by probabilities or possibilities. The fact that a given thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). See also *Tintec Industries, Inc. v. Top-USA Corp.*, 63 U.S.P.Q.2d 1597, 1599 (Fed. Cir. 2002). When relying upon the theory of

inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

The Examiner found that “Carr teaches a process for preparing an enhanced-solubility milk protein concentrate comprising providing a milk protein concentrate in aqueous solution/suspension and adding at least one monovalent salt (e.g. sodium chloride) in an amount that confers enhanced solubility on the product”. Office Action, page 3. The Examiner further found “Carr teaches the use of the prepared milk protein concentrate in the preparation of cheese wherein protein and concentrated fat (i.e. cream) are added to the enhanced solubility milk protein concentrate (see Example 9), wherein the cheese is then prepared by a conventional process”. *Id.* The Examiner further found that “[a]n increase in the emulsion capacity and stability would be no more than inherent and/or obvious to that of Carr as the same components and process steps are used.” *Id.*

Applicant respectfully disagrees with the Examiner’s characterization of Carr. Carr is concerned with preparing a dried MPC that has enhanced solubility when reconstituted, *not* a product that enhances emulsification of fat in water. Moreover, the process of Carr differs in substantive and important ways from the claimed processes.

In particular, Carr discloses “that surprisingly the addition of salt prior to drying is necessary to confer improved solubility.” Carr, page 11, ll. 1-2. Example 3 of Carr discloses that the solubility of MPC85 in water was the same as the solubility of MPC in a salt solution mimicking cation enhanced powder. Carr, page 10, line 28 to page 11, line 2. Therefore, in order to confer improved solubility, Carr requires *both* that the salt is added prior to drying and that the solution is then dried to form MPC. *Id.* Example 9 of Carr discloses adding fresh cream to fresh skim milk and subsequently adding various compositions of *dried* MPC85 to the mixture of fresh cream and fresh skim milk. Carr, page 13, ll. 13-25.

Claim 38 recites in part “mixing the concentrated protein with water to form a hydrated protein solution; adjusting the ionic composition of the *hydrated* protein solution” and “mixing the *hydrated* protein solution with a concentrated fat to form a first food product”. Carr does not teach this feature because Carr requires that the MPC solution be dried in order to confer

enhanced solubility. There is no teaching of adjusting the ionic composition of a hydrated solution. To the contrary, Carr explicitly teaches that salt is added prior to drying and prior to reconstitution. Therefore, Carr fails to anticipate Claim 38 for at least this reason.

Carr also discloses that “[t]he term ‘enhanced solubility’ refers to the property of a product which on reconstitution into a 5% w/v solution provides less sediment on centrifugation for 10 minutes at 700g relative to the corresponding product without salt treatment.” Carr, page 2. That is, Carr is concerned with the solubility of the dried MPC when it is reconstituted (so that it doesn’t form nuggets), not its ability to emulsify fat in water. There is simply no disclosure in Carr regarding emulsification properties.

With respect to the Examiner’s suggestion that the claimed process is inherent, the Examiner has only provided a conclusory statement which clearly does not meet the required burden for showing inherency. When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the teachings of the applied prior art. Ex parte Levy, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added). The required reasoning has not been provided. Because Carr teaches a different process for forming a product with different properties, it can not inherently teach the claimed methods.

Carr focuses on *enhancing the solubility* of dried MPC. Enhanced solubility and enhanced emulsification are *not* synonymous. Briefly, the highly polar nature of water molecules prevents water from effectively interacting with the distinctly non-polar fat or oil molecules. The polarity differences therefore prevent fats/oils from dissolving in water, and force water and fat/oil to separate into distinct, independent phases, unless stabilized as emulsions by emulsifiers. Emulsifiers are typically molecules with two distinctly different sections:

- A. a highly polar section that interacts with the highly polar water molecules, and
- B. a highly non-polar section that interacts with the non-polar fat/oil

The shape or conformation of the molecule allows both sections to freely interact with components of the respective polarity: i.e. the highly polar section must freely interact with water, while the non-polar section simultaneously must freely interact with the fat/oil phase. Therefore, effective emulsifiers typically have both the correct molecular structure (i.e. both the separate polar and non-polar sections) and the correct conformation (i.e. the correct shape

positioning the separate sections so that these sections simultaneously and freely interact with the respective components).

Increasing the *solubility* of any particular protein does not inherently enhance the ability of that protein to emulsify fat. Indeed, enhancing the solubility of most proteins may proportionally decrease the ability of those proteins to emulsify fat. The solubility of a protein depends upon the protein assuming a conformation that maximizes the exposure of the polar amino acid groups in the protein's primary structure to water. For high solubility, these conformations simultaneously maximize the surface exposure of the polar amino acids and minimize the surface exposure of the non-polar amino acids, because the inability of non-polar amino acids to interact with water proportionally reduces solubility. Therefore any protein conformation maximizing solubility would fold the non-polar amino acids into the protein interior, essentially masking the inherent incompatibility of polar and non-polar compounds. Positioning the non-polar amino acids within the protein interior renders these sections less capable of simultaneously interacting with fat and water. Thus, the ability of these proteins to act effectively as emulsifiers is reduced. Such conformations proportionally increase the solubility of the protein, while simultaneously reducing the ability of that protein to effectively emulsify fat. The Examiner has provided no basis for a conclusion that Carr's MPC has increased *emulsion* capacity. Therefore, Carr fails to inherently disclose "adjusting the ionic composition of the hydrated protein solution to enhance its ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein". Carr also does not teach this feature explicitly. Accordingly, Applicant respectfully requests withdrawal of this rejection for at least this reason.

Carr also fails to disclose explicitly or inherently "mixing the hydrated protein solution with a concentrated fat to form a first food product" as recited in Claim 38. As discussed above, Example 9 of Carr discloses adding fresh cream to fresh skim milk and subsequently adding various compositions of *dry* MPC85 to the mixture of fresh cream and fresh skim milk. Carr, page 13, ll. 13-25. Therefore, Carr fails to disclose mixing the *hydrated* protein solution with a concentrated fat. Accordingly, Applicant respectfully request withdrawal of this rejection for at least this reason.

Obviousness

The Examiner also rejected Claims 2-8, 10-13, 16-22, and 38 under 35 U.S.C. § 103 as obvious over Carr.

Carr is available as a prior art reference under 35 U.S.C. § 102(e) for claims entitled to the priority of the provisional application, as discussed above including at least Claims 38, 2-8, 10-13, 16, and 27. 35 U.S.C. § 103(c)(1) states:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c)(1).

Carr and the present application were both owned or under a common obligation of assignment to Fonterra Co-Operative Group LTD. at the time the claimed inventions were made. The Assignment of the present application to Fonterra Co-Operative Group LTD. is recorded at Reel 014483, Frame 0043. The Applicant for Carr is the New Zealand Dairy Board. In October of 2001 Fonterra Co-Operative Group LTD. was formed by the merger of the New Zealand Dairy Board with the New Zealand Dairy Group and Kiwi Co-operative Dairies. See the attached history of Fonterra Co-Operative Group LTD, which can be found at <http://www.fonterra.com/wps/wcm/connect/fonterra.com/fonterra.com/our+business/fonterra+at+a+glance/about+us/our+history>. Therefore, Applicant respectfully submits that Carr is not a proper reference under 35 U.S.C. § 103 to at least Claims 38, 2-8, 10-13, 16, and 27.

As discussed above, Carr fails to anticipate Claim 38 explicitly or inherently. Further, Carr cannot be applied under § 103(c) to at least Claims 38, 2-8, 10-13, 16, and 27. Accordingly, Applicant respectfully request withdrawal of these rejections of Claims 38, 2-8, 10-13, 16, and 27.

Even assuming *arguendo* that Carr is a proper reference under § 103 to Claims 17-22, Carr does not render Claims 17-22 obvious. As discussed above, Carr does not disclose the features of Claim 38 explicitly or inherently. In particular, Carr as modified by the Examiner does not disclose "adjusting the ionic composition of the *hydrated* protein solution to enhance its

ability to emulsify fat in water as measured by at least one of increased emulsion capacity (EC) and increased emulsion stability (ES) in comparison to untreated protein". This is more than an obvious variation of the disclosure of Carr. As discussed above, Carr discloses "that surprisingly the addition of salt prior to drying is necessary to confer improved solubility." Carr, page 11, ll. 1-2. Example 3 of Carr discloses that the solubility of MPC85 in water was the same as the solubility of MPC in a salt solution mimicking cation enhanced powder. Carr, page 10, line 28 to page 11, line 2. Therefore, in order to confer improved solubility, Carr requires both that the salt is added prior to drying and that the solution is then dried to form MPC.

Carr discloses adding salt to milk and forming dried MPC with increased solubility in cold water. The skilled artisan would understand that there are different concerns regarding modifying protein to enhance cold water solubility versus emulsification properties. There is no disclosure or reason to modify the process of Carr to improve emulsification properties, much less any suggestion how to do so. Thus, Applicant submits that there is no reason to modify Carr.

Further, Carr teaches away from improving emulsification properties. As discussed above, any protein conformation maximizing solubility folds the non-polar amino acids into the protein interior, essentially masking the inherent incompatibility of polar and non-polar compounds. Positioning the non-polar amino acids within the protein interior renders these sections less capable of simultaneously interacting with fat and these proteins will have a reduced ability to effectively act as emulsifiers. Therefore, the disclosure of Carr regarding enhanced solubility teaches away from enhanced emulsification properties. Accordingly, Applicant requests withdrawal of this rejection for at least this reason.

Moreover, modifying the MPC of Carr to improve the emulsification properties would adversely affect the cold water solubility of the MPC because of the interaction of non-polar amino acid groups and water. This change would render Carr unsatisfactory for its intended purpose, to produce MPC with enhanced cold water solubility. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason.

In addition, for the reasons discussed above, the modification proposed by the Examiner would change the principle of operation of Carr. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Accordingly, Applicant respectfully requests withdrawal of the rejection for at least this reason as well.

Applicants also note that Sadowsky, the secondary reference cited with respect to Claims 33-37, does not make up for the deficiencies of Carr.

For the reasons discussed above, Carr fails to anticipate or make obvious Claim 38. Accordingly, Applicant respectfully requests withdrawal of the rejections of Claim 38. Additionally, Applicant submits that Claims 2-8, 10-13, 16-22, and 39-42, are not anticipated or made obvious by Carr, not only because they depend from Claim 38, but also on their own merit.

Further, new Claims 39-42 recite "wherein the first food product comprises high fat cream." "wherein the high fat cream comprises 70% fat or greater", "wherein the first food product comprises plastic cream" and "wherein the plastic cream comprises about 80% fat", respectively. Carr and Sadowsky also fail to teach these features.

The Combination of Carr and Sadowsky Does Not Make Claims 33-37 Obvious

Claims 33-37 stand rejected under 35 U.S.C. § 103 as unpatentable over Carr in view of U.S. Patent No. 6,358,551 to Sadowsky.

Claim 33 recites in part "homogenizing the combined milk and fat to produce cream". Sadowsky fails to disclose a method for making cream. Rather, Sadowsky discloses a method for incorporating concentrated milkfat into milk to form a *slurry*. Col. 5, ll. 30-50. Sadowsky discloses that "[g]enerally, the amount of concentrated milkfat added to the first portion of the reduced-fat raw milk is about 4 to about 10 percent." Col. 5, ll. 43-45.

Example 1 of Sadowsky discloses forming a slurry with 8.4% fat. Example 2 of Sadowsky discloses forming a slurry with 3.9% fat. The slurries disclosed in Sadowsky do not contain enough milkfat to qualify as a cream under any of the FDA Standards of Identity promulgated in 21 C.F.R. § 131. For example, the FDA Standards of Identity state that heavy cream (21 C.F.R. § 131.150) contain not less than 36% milkfat, light cream (21 C.F.R. §

131.155) contain not less than 18% milkfat and not more than 30% milkfat, and light whipping cream (21 C.F.R. § 131.157) contain not less than 30% milkfat and not more than 36% milkfat.

Therefore, Sadowsky fails to disclose “homogenizing the combined milk and fat to produce cream” as recited in Claim 33. Further, this is more than an obvious variation of Sadowsky. There is also no reason to modify Sadowsky to produce a cream.

Carr fails to make up for the deficiencies of Sadowsky. Carr also teaches away from “mixing nonfat dry milk comprising milk proteins with water to form reconstituted skim milk, wherein the water comprises a monovalent salt prior to mixing” as recited in Claim 33. See Example 3 of Carr, page 10, line 28 to page 11, line 2. Accordingly, Applicant respectfully requests withdrawal of this rejection.

For the reasons discussed above, the combination of Carr and Sadowsky fails to make Claim 33 obvious. Accordingly, Applicant respectfully requests withdrawal of the rejection of Claim 33. Additionally, Applicant submits that Claims 34-37 and 43-45, are not made obvious by Carr/Sadowsky, not only because they depend from Claim 33, but also on their own merit.

Further, new Claims 43-45 recite “wherein the cream comprises more than 36% fat”, “wherein the cream comprises high fat cream”, and “wherein the cream comprises plastic cream”, respectively. Carr and Sadowsky also fail to teach these features.

No Disclaimers or Disavowals

Although the present communication includes alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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